THE UNITED STATES DEPARTMENT OF AGRICULTURE

In the Matter of:	)	
	)	
PEST RISK ASSESSMENT	)	Docket No. 99-079-01
	)	

Montpelier Room
Washington Court Hotel
525 New Jersey Avenue, N.W.
Washington, D.C. 20005

Wednesday,
November 10, 1999

The hearing in the above-entitled matter was convened, pursuant to notice, at 10:15 a.m.

BEFORE: MICHAEL A. LIDSKY, Esquire
Assistant Director, Regulatory Coordination

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P R O C E E D I N G S

(10:15 a.m.)

MR. LIDSKY: Gentlemen, good morning and welcome to the public meeting being held by Plant Protection and Quarantine Programs, PPQ, of the Animal and Plant Health Inspection Service, APHIS, on the commodity pest risk analysis process.

My name is Mike Lidsky. I'm assistant director for regulatory coordination on the APHIS Plant Health Program staff. I've been asked by our deputy administrator, Dr. Rick Dunkle, to be the moderator for today's hearing.

The purpose of today's meeting is to give interested persons an opportunity to present comments on the process being utilized by PPQ programs, relative to the production of pest risk assessments for commodities. Specifically, we're interested in hearing your views to improve public involvement in the process and public access to information about new and pending pest risk analyses.

Notice of today's hearing was published in the Federal Register of October 8, 1999, on pages 54859 through 60 and indicated that there would be a 60-day comment period that closes on December 7. We're holding this meeting on improvements to the pest risk analysis process for commodities as a result of several distinct reasons and several distinct events. You might say that everything sort of came together about the same time.

As we noted in the Federal Register, this initiative is, in part, a result of the safeguarding system review that was conducted by the National Plant Board at the request of PPQ officials. The National Plant Board is a

professional organization of state plant protection officials whose goal is to advance and protect agriculture, horticulture and forestry at state, national and international levels, who work in concert with federal counterparts, primarily PPQ officials, to accomplish items of mutual concern.

The results of the review were made available to PPQ on July 1 in a report entitled "Safeguarding American Plant Resources," as a stakeholder review of APHIS PPQ's safeguarding system. The report addresses a number of areas within the safeguarding system, where change is recommended. The report is available in its entirety on the APHIS website at www.aphis.usda.gov.

However, the area of particular concern related to today's meeting is the use of risk assessment, risk mitigation and risk communication within PPQ programs. Most of the emphasis in the report relating to risk analysis was on the use of pest risk analysis activities relating to international trade and our obligations under international agreements, with a particular focus on the role of pest risk analysis in supporting decisions and justifying quarantine actions regarding the importation of plants and plant parts for propagation or consumption.

The report did note the role of pest risk analysis in PPQ's biotechnology- and organism-permitting programs. However, there was no detailed discussion of those aspects of PPQ's risk analysis activities in those areas. The higher visibility accorded to PPQ's commodity pest risk analysis process can be attributed to the important role that pest risk analysis plays in supporting regulatory

changes that are necessary before a new commodity from a particular foreign country may be imported into the United States.

The safeguarding report is deemed to be so significant in shaping the future of PPQ that Dr. Dunkle took the unprecedented step of sending a copy of the report to each PPQ employee's home. The report made in excess of 300 recommendations. The review of these recommendations is a large undertaking.

These recommendations must be thoroughly evaluated to determine their feasibility and the contributions they can make to enhancing the safeguarding system. To facilitate the evaluation process, 17 issue areas have been tentatively identified into which the recommendations will be grouped. Group leaders have already been identified to conduct some initial assessment of the recommendations and ensure the issue areas have been correctly identified. Based on their work, the issue areas may be modified before moving forward with the evaluation.

Just very quickly, the 17 issue areas are: information technology, information management, organizational structure and leadership, employee development, pest detection and response, civil penalties, user fees/alternative funding, risk assessment, risk management, science and technology, international issues, permits, authorities, staffing, public information/education, stakeholder collaboration, and taxonomic services.

Ms. Paula Henstridge, formerly of Legislative and Public Affairs, has been assigned to PPQ to spearhead

coordination and implementation of the safeguarding recommendations. But even before the safeguarding report was released in July, PPQ was aware of the need to make improvements to its pest risk analysis processes. It's no secret that many of the issues raised in the safeguarding system report are similar to issues raised and comments submitted pursuant to proposed regulatory changes and in other correspondence directed to PPQ.

Consequently, PPQ management commissioned the agency's business practices team, which is an internal group that examines the way APHIS units conduct their operations, to commence a PPQ-wide review of the program's risk analysis processes. This has resulted in the formation of three working groups that are responsible for addressing the following areas: benchmarking, comparing how the process works in PPQ compared to other program areas within APHIS, as well as those of other government agencies; customer and stakeholder feedback -- their mission is to obtain feedback from our customers and stakeholders, as the name implies; and lastly, a group whose job is to document the PPQ risk analysis process in order to identify any redundant or unnecessary activities for the design and implementation of improvements. Mr. Ray Nosbaum and Mr. William Wade are spearheading the businesses and practices team review.

As part of our benchmarking activities, we will be convening a symposium to review and discuss the existing international standards for pest risk analysis and the current state of the art, relative to conducting pest risk analysis and assessments. At the symposium, we will also discuss comments received from today's public meeting, as

well as written comments made in response to this initiative. We will provide an update on where we are, with the review being conducted by the APHIS business practices team.

We are tentatively planning on holding the symposium during the first quarter of calendar year 2000. The specifics of the symposium will be published in a Federal Register notice when such details are available.

The Federal Register notice announcing today's meeting emphasized that we are particularly interested in improving the transparency of our process and providing an opportunity for interested parties to participate prior to rulemaking. We certainly recognize that by increasing the transparency of the process and providing an opportunity for interested parties to participate prior to rulemaking, that such collaboration and consultation will increase the amount and quality of information available to risk assessors. And of course, that's a very desirable outcome.

In the notice announcing today's hearing, we identified four areas that we hope commenters will pay particular attention to. Qualitative versus quantitative risk assessments: What specific criteria could be used for determining which type of risk assessment is appropriate in a given situation.

Preparation of assessments: Should exporters or exporting countries be allowed to conduct pest risk assessments under APHIS guidance as a means of expediting the handling of requests for commodities to be allowed entry into the United States?

Notification of the initiation of a pest risk analysis: Should APHIS publish a notice in the Federal Register to notify the public whenever PPQ initiates a pest risk analysis pursuant to a request for a commodity to be allowed entry into the U.S.? Should such a notice be reserved for the more complex nonroutine decisions?

And use of a web-based tracking system: This is a system that could be used to enhance the transparency of, and facilitate participation in, commodity pest risk analysis development by providing the public with timely information about the receipt of an import petition, the status of those petitions, the status of those pest risk analyses associated with the petitions, and provide a mechanism for the public to offer information and feedback regarding petitions and pest risk analysis. Would such a system be useful and would it preclude the need to publish notices in the Federal Register, as previously discussed?

Well, before concluding my remarks, I'd like to give you a few necessary administrative details. Today's session, of course, is being recorded. The court reporter for today's session is Ms. Beth Roots of the Heritage Court Reporting service. A copy of the transcript can be obtained by contacting Heritage at (202) 628-4888 and paying a fee. However, once we obtain a copy of the transcript, a copy of it will be placed on our website.

I'll call speakers somewhat in the order in which they registered. We've been asked to make some adjustments and we'll make those accommodations. After all registered persons have been heard, I'll ask if there's any nonregistered persons that wish to speak and, of course,

your statement will be made part of the written record. I'll ask that anyone that reads a prepared statement please provide me with two copies before the conclusion of the hearing.

We're scheduled to conclude at 5 p.m., but as stated in the Federal Register, if all persons who wish to speak have done so, we'll conclude early. Any comments that we receive in connection with this matter can be viewed in the APHIS public reading room. That is in Room 1141 of USDA South Building, 14th and Independence Avenue, S.W. It's open from eight to 4:30, Monday through Friday, not on holidays, and we suggest that before visiting the reading room, you call ahead on (202) 690-2817, to insure that someone is there to assist you.

Any additional comments should be submitted to our regulatory analysis and development staff. They're in Suite 3C03, 4700 River Road, Unit 118, Riverdale, Maryland. You should indicate that your comments are in reference to this proceeding, which is docket no. 99-079-01. All this information is in the Federal Register notice, which we have available on the registration table.

Lastly, and perhaps most importantly, the comment period for this particular matter is December 7 and comments must be received by APHIS by that date. So without further ado, we'll ask Craig Regelbrugge -- I hope I pronounced that right -- to come up and share his comments with us, please.

MR. REGELBRUGGE: Dr. Lidsky and ladies and gentlemen, good morning. My name is Craig Regelbrugge. I'm here on behalf of the American Nursery and Landscape Association. We are very pleased to note that the

"Safeguarding American Plant Resources" review has been a catalyst for APHIS's effort to seek public input into its approaches on risk analysis, including risk communication.

As a co-chair of that review, I wish to commend APHIS for its serious commitment to implementing the report's recommendations. Frankly, we believe that the simple act of authorizing and initiating the review has already demonstrated APHIS's desire to transition to new ways of doing business in an environment characterized by unprecedented international movement of people, goods, and species.

I wish to make a few general remarks on some of the concepts and questions posed in the Federal Register notice and a couple of specific remarks. My remarks today will be more about the process, conclusions, and intent of the safeguarding review. We also expect to file additional comments on behalf of the organization that I represent.

First, it is clear that APHIS already recognizes the need to modify its practices relative to risk analysis to insure that its assessments can be conducted in a timely manner consistent with international obligations, that they are scientifically robust, and that external stakeholders are afforded the opportunity to have early and meaningful input into the process.

Many other federal agencies and, indeed, APHIS's peers in other countries are facing pressure to do the same. For example, the U.S. Environmental Protection Agency, under tremendous scrutiny as to how it will implement the Food Quality Protection Act, is making a number of process

modifications to improve both the quality of its assessments and process transparency.

While the rancorous debate has not totally ended, I believe all would agree that the process has been improved greatly. The safeguarding review concluded that APHIS's risk analysis process as it exists today is unsustainable. Insufficient resources exist to work through both current demands and the substantial backlog. Differing perceptions of risk and scant external communication about process priorities and pending actions have contributed to destructive political interference.

Information systems and communication loops are inadequate to ensure an effective feedback loop of interception information from ports of entry back to headquarters, to be used in refining assessments, mitigation strategies, and for the necessary continuous improvement of the system.

The review panel fully understood and appreciated the need for risk analysis policy that meets the intent of international obligations and is sensitive to the reality that what we do unto our trading partners, they will do unto us. It is for this reason that the review panel did not recommend such time and resource intensive measures as a full, mandatory scientific peer-review process for every APHIS decision. Rather, the improvements suggested by the panel are realistic and intended to encourage meaningful collaboration upfront and a transparent and robust process throughout.

We applaud the decision to have the business practices team lead the effort to review and suggest

improvements to the APHIS risk analysis process. This team must take very seriously the need to seek outside input and ideas. Input must be sought and received from cooperators, industry, and the environmental community. In the end, APHIS PPQ has no choice but to excel at risk analysis and to be recognized by all its stakeholders for that excellence.

I'd like to make a couple of very specific remarks. First, on the areas dealing with notification and tracking systems, the review strongly supported the establishment of a notification mechanism for requests or other agency actions that trigger the need for a risk assessment. Establishment of a stakeholder registry was seen as facilitating such notification. We did not believe that Federal Register notification should always be a necessity, but a workable, web-based tracking system, coupled with some type of registry that's consistent with federal administrative procedures requirements should suffice for actions other than proposed and final rules and major notices.

We supported notification and tracking for both routine and nonroutine decisions. In the Australian model -- and in our view, Australia is a couple years ahead of us in the process in many of these areas, based on a similar external review that was conducted back in the mid-1990s. The Australian model was reviewed favorably by our team, and in that model, the routine and nonroutine designations refer to whether a risk analysis can be performed by an in-house team or if there's a needed infusion of outside expertise.

In our view, early notification and collaboration with stakeholders may need to precede a decision as to

whether the required assessment should be considered routine or nonroutine. APHIS may not be in a position to decide on its own in all cases.

The following quote comes from the Nairn Report of the Australian quarantine system: "Import risk analysis should be conducted in a consultative framework, with agreed priorities and timetables. Consultation should be early and broad, with the inclusion of all relevant stakeholders. Early consultation should help to engender the partnership approach advocated by the review committee, and avoid the adversarial and confrontational approach that has characterized import risk analysis of some proposed imports in recent years."

In our review, we simply could not have said it better ourselves. While the safeguarding review process differed, the Nairn study and resulting report offered an excellent model that we believe should be closely studied for both guiding philosophy and criteria. The Nairn report described a number of factors that should be considered when deciding whether an assessment is routine or nonroutine and the type of assessment, qualitative or quantitative, that should be conducted.

I've detailed some of those in my remarks today. In the interest of brevity, I will not go over those criteria, but they are included in my written remarks.

As far as the question of preparation of risk assessments by outside parties, the safeguarding review concluded that business as usual is simply not an option in the area of risk assessment. The report, as a result,

discussed a range of options, including cost recovery and allowing outside parties to contribute to assessments.

Obviously, several factors will contribute to the process of setting a priority internally in APHIS for dealing with the request. They might include the source of the request, the quality of the application and supporting materials, the amount of time the request has been pending, and the expected societal benefit. Offering outside parties the opportunity to at least contribute to or partially complete an assessment may simply constitute a wise use of resources and allow those certain requests to move further up the priority list.

It may be that outside parties can best contribute to some of the upfront analysis, such as cataloging and reviewing earlier related PRAs and contributing to pest list development. A preparer of such supporting information should, of course, be in full conformance with established international and APHIS guidelines. Transparency at each step of the way will be critical to engendering confidence in the process.

In conclusion, the review panel offered a wide array of recommendations that I believe will strengthen APHIS's ability to fulfill its safeguarding mission. We concluded that many of these recommendations can be implemented with existing authorities and, in many cases, within existing or expected resources.

We also recognize that considerable change and improvement are needed to inspire heightened trust and confidence in the process. We recognize that such change will require that the department, agency, and stakeholders

value the importance of risk analysis as a core competency for APHIS. We, as a group, are pleased to note the APHIS commitment to move forward, as has already been evidenced by the Federal Register notice and this hearing.

Plant industry stakeholders are equally committed to supporting and facilitating successful implementation of the review. Toward this goal, we are forming a coalition that will be known as the Plant Safeguarding Alliance. We expect this to be a broad-based coalition of agricultural groups that care about the safeguarding mission. We look forward to collaborating early and often with APHIS and expect the communication links with this coalition to be very strong as implementation proceeds.

Again, we expect to file more detailed written comments before the December 7 deadline, but appreciate this early opportunity to share our views. Thank you.

MR. LIDSKY: Thank you. Our next speaker is Jean-Mari Peltier.

MS. PELTIER: Good morning. My name is Jean-Mari Peltier and I am the president of the California Citrus Quality Council. The California Citrus Quality Council for 30 years has been representing our state's citrus industry to assure that our products in both international and national markets of trade are high quality and wholesome. We welcome this opportunity to participate in this, which we see as just one of many steps that the Animal and Plant Health Inspection Service has taken to open up this process to public comment and review, and we think you're to be commended for that.

Obviously, from the perspective of the California citrus industry, this is a critically important process because so very much is at stake. According to our statistics, California exports approximately a third of its annual production, and in 1998, over $200 million worth of California citrus found its way into our best markets in the Pacific Rim, in Japan and South Korea, Taiwan and Hong Kong.

Clearly, California citrus growers live and die in the export market. But at the same time, we're extremely vulnerable to infestation from exotic pests and diseases. Obviously, we're considered a minor crop in the view of the chemical producers and so protection tools are not always available to us to help in the case of having an infestation.

Further, the most recent activity that we've had in California with the infestation of an exotic glassy-wing sharpshooter has brought all too closely into focus the vulnerability that we have potentially from infestation with unwanted disease pests. In this particular case, with glassy-wing sharpshooter, this is an excellent vector for Pierce's disease, which affects not the citrus industry, but the grape industry. The difficulty is that this pest overwinters in citrus and is also believed to be an excellent vector for citrus variegated chlorosis, a disease that we don't have in California and don't want in California. It's the scourge of international citrus producers and something that we're very concerned about, in conjunction with this new infestation with glassy-wing sharpshooter. So once again, to put in perspective, we're

very, very much interested in your activities and welcome this opportunity.

On the issue of benchmarking that was raised, I'd like to bring in perspective that I have after my three most recent years of activity with the California Environmental Protection Agency, in which we were involved with risk assessments underevaluating the risks associated with pesticides.

In that position as the chief deputy director of the Department of Pesticide Regulation, I also served on U.S. EPA's Tolerance Reassessment Advisory Committee, which was charged with implementation of the Food Quality Protection Act. And if you'll allow me, I think there are a number of parallels that APHIS should consider in evaluating the way it establishes this process of risk assessment, because I think that agency was charged with a massive undertaking in reevaluating the way its risk assessments would be conducted post passage of the Food Quality Protection Act.

In the months that followed passage of that act, the agency was stymied in its ability to move anything through the process, and what we found was that in risk assessment, the rules of the road hadn't been established. One risk assessment would use one set of tools and one set of criteria, one set of default assumptions in the areas where there wasn't empirical data. In the next risk assessment, another process would be in place.

As a result of action by Vice President Gore, a committee called the Tolerance Reassessment Advisory Committee was established. And within that, the agency

moved from a process in which it was absolutely nontransparent and variable from one risk assessment to the next, to one in which the rules of the road, whether you agreed with them or not, were at least fully transparent and people understood how their risk assessment would be conducted.

And I think what would be parallel here is first of all, use of national and international panels for development of specific science policies that will be employed in the area of risk assessment. These could be established for use by APHIS, either on a formal or an ad hoc basis. The idea would be not for peer review of individual risk assessments, but to use, as needed, for establishment of specific science policy papers to support the conduct of risk assessment.

Secondly, development of empirical data, where possible. Obviously, you're dealing with a different situation where you have pesticide registrants that are charged with the responsibility of conducting individual studies to pinpoint individual risks. But I think that it's incumbent upon APHIS to call on the exporting countries to provide as much empirical data as possible to aid in the risk assessment.

I think that APHIS should consider establishment of advisory committees similar to those that are in place with ARS, similar to those in place at the Foreign Agricultural Service, including the Agricultural Technical Advisory Committee on Trade, calling together industry interests to provide input to APHIS on both import and export priorities.

Finally, to kind of underscore the comments that were made by Mr. Regelbrugge, I think the issue of calling for adequate input upfront and collaboration is an excellent one. I'd like to commend APHIS for a recent workshop that they held out in California in which they allowed the regulated community, allowed growers, shippers, and representatives of the State Department of Agriculture, as well as university experts, to comment on a proposal informally, dealing with Florida's citrus canker. And that informal review, going out to the field and allowing industry to provide input along with the university, was absolutely excellent.

I think, finally, it's pretty clear that additional resources are going to be needed for APHIS to be able to conduct the level and the kind of robust risk assessments that industry is calling for. The idea of a web-based tracking system to provide timely input is excellent, but I would agree with Craig that there is a need to assure that there's also a registry of interested individuals to have access to information early on on proposals, to allow additional input.

We are in the process of putting together a formal statement on behalf of the California citrus industry, on behalf of CCQC, and will be filing formal statements in December. But once again, thank you for this opportunity.

MR. LIDSKY: Thank you. Our next speaker is Nancy Williams, please.

MS. WILLIAMS: Good morning, and good morning to everyone in the audience, as well. I feel a little strange. I'd like to be talking to everyone, also. I'm with the firm

of Schramm & Williams here in Washington. I'm here today representing the U.S. Citrus Science Council. My firm also represents a very broad array of California and Arizona agricultural commodities and, while I'm here speaking particularly for the Citrus Science Council, I can say with great vehemence that all of California and Arizona agriculture is watching these proceedings and these efforts with much interest and they recognize how vital it is to everyone's future.

To give you a little background about myself, I've been in Washington for over 20 years. The better part of that 20 years I have spent either actually writing regulations in different federal agencies, working on Capitol Hill with legislation, or representing clients in the private sector. Some of those rulemakings I was involved in were highly controversial, highly visible, and we understand the challenges that face agencies when an agency is plowing new ground or getting into new areas.

The U.S. Citrus Science Council asked Dr. Edmund Crouch of Cambridge Environmental to come to this meeting, and the focus of the Science Council's comments will be on the risk assessment process, since we believe that is the critical aspect of APHIS's activities in this area. However, I did want to make a few comments about the overall process, since APHIS staff had indicated that would be appropriate at this meeting.

I think that first I'd like to say all of the industry gives great credit to all of the folks involved in the National Plant Board study, both at APHIS and all of the folks who worked on it from the outside. A truly enormous

amount of work, incredible thoughtfulness and detail in that report, and it is, I think, certainly the best report of that type that I have seen in my time here.

But one of the statements in that report is really what we see as leading probably to the need for this meeting and, we hope, many more meetings. And the conclusion in the Plant Board report that has really gotten the attention of many of the folks I represent is the statement that, "APHIS is caught in a dichotomy between trade policy and pest exclusion that may be too burdensome to sustain." That is a very, very serious comment. And again, all the folks I represent see it as the industry's responsibility to work with APHIS and engage in whatever activities are necessary, so that APHIS does not continue to be caught in this dichotomy and that APHIS can continue to be the agency that the world looks up to in this area.

Mr. Regelbrugge and Ms. Peltier have mentioned stakeholder involvement, early stakeholder involvement. That, of course, is one of the primary goals and has been one of the primary comments of the U.S. Citrus Science Council. But once one gets beyond the early stakeholder involvement, there's also a desperate need within APHIS, we believe, for the process, the procedures, and the rules to be reduced to regulatory language, or at least to guideline language.

As Ms. Peltier referred to, in EPA's case, no one knew who -- they didn't know what the rules of the road were. We have found in the case of what APHIS is doing at this time, particularly with respect to import petitions, we don't know what the rules of the game are. And that is one

of the comments that we've heard most often from the growers. If we just understood what the process was, if we understood what the concepts were that we were working with, if we understood how this decisional process was going to move forward, then we can react and we can engage. But at the current time, we find very little in either guideline language or regulatory language that gives us those parameters.

And as just one example of that, when we were faced at commenting on a so-called systems approach, we found that there is no definition of what a systems approach is, in APHIS regulations. There is no -- we were not able to even find a guideline that defined what a systems approach was. And we think other concepts -- we think that there need to be very specific guidelines on the types of data that should be submitted to APHIS, the quality of the data, the types of data, the time frames covered.

We all recognize, of course, that we are dealing with science here and that there has to be flexibility within guideline or regulatory language, but that is the case with any regulatory agency. They have to find ways to find flexibility within a regulatory framework. I've learned a lot since I've been working closely on APHIS activities. I readily admit I am not a scientist, and I come to the task not with a scientific background, but with a legal background. And one of the things, one of my observations has been that as the policymakers in our country and on Capitol Hill have begun to struggle with more and more difficult issues, they have sort of shifted the

burden onto our scientists in this country and said, let the scientists decide. We'll rely on good science.

Unfortunately, in our society, the lawyers and the scientists speak almost two different languages. And it's been a real learning experience for me, and I think that we all have a long way to go to bring together those two different worlds of legal concepts, under which regulatory agencies work, and scientific concepts, which are so central and so key to the future of APHIS activities.

So I do not want to take any more time, and Dr. Crouch has a detailed presentation, but I would just like to close -- I'd like to thank APHIS for holding this meeting. We think it's a very, very important step and we commend the agency, as others have done. We hope there will be more, many more of these. But at the risk of sounding overly dramatic, I would just like to close by saying we believe the future of U.S. agriculture truly, truly depends on APHIS getting this effort right. Thank you very much.

MR. LIDSKY: Thank you very much.

Dr. Crouch, please.

DR. CROUCH: Can you get me if I speak here?

THE REPORTER: Yes.

DR. CROUCH: Thank you. My name is Edmund Crouch. I work for a company called Cambridge Environmental and we are risk assessors. And I was asked to come here today to speak about risk assessment. I was asked by the U.S. Citrus Science Council, but the comments that I'm making are my own. They don't apply to anybody, not even me.

(Laughter.)

DR. CROUCH: What I would like to talk about a little bit is methodology for risk assessment. And nothing that I say today is new. It's all been said before, as far as I can tell, usually much better than I will say it today and more forcefully in many cases, and I'm going to skip over the first three of my slides, because I want to come back to them, because they really summarize, essentially, what I'm going to say.

I'll be pointing out in places where these things have been said and where I can at least get an introduction to the sort of concept that I want to talk about.

The first thing that anybody needs to do when contemplating doing a quantitative risk assessment is to have a very clear description of the task that they're involved in. That clear description, I suggest, has been lacking in much of what's gone before. For example, what is it that you're really concerned with in a quantitative risk assessment -- what are you concerned about? Is it prevention of the establishment of a pest if this is a pest risk assessment? I mean, the same concept applies for all quantitative risk assessments.

And I should say, quantitative risk assessment has been mainly applied to health risk assessment, human health risk assessment. That's almost what it means. If you talk to anybody about risk assessment, they generally understand human health risk assessment. If you say PRA to a risk assessor, that doesn't mean pest risk assessment, that means probabilistic risk assessment. You've got a language gap immediately.

What is it -- is it prevention of the establishment of a pest? Do you want to minimize the probability of establishment? Do you want to minimize the risks of pests once they get established? Do you want to provide some sort of acceptable risk for the probability of prevention, minimization, etc., etc.

These are not the same. And they have different indications for what you do in a probabilistic or a quantitative risk assessment in general, and specifically in a probabilistic one.

And before you can start, you need -- description, because that very often suggests directions that the analysis will then take.

One thing that I seem to have -- that I missed entirely in the probabilistic or the quantitative risk assessments that I have seen is that risk is not just probability. It's some sort of convolution of probability and consequence, and there has been a notable lack of discussion of consequence. I should say that my principal introduction to pest risk assessment was in evaluating the U.S. citrus -- the citrus import from Argentina, the risk assessment performed for that.

The concept of risk being probability and consequence is absolutely fundamental to risk assessment. It tends to get hidden a bit when we're talking about health risk assessment, because everybody knows what you're talking about there. It's usually risk of death or risk of human adverse health consequences in a defined way.

But in pest risk assessment, I haven't seen any good evaluation of what sort of multiplication this is.

Notice I didn't say "multiplied by." I've got this weird symbol, which is a mathematical thing used, "some sort of convolution of," it means. And we don't know yet what. That depends on what you're aiming at. Some one of the things that you've got to do is define what it is you're after.

And then -- I've given a reference there to one of my own books, where this is put in. In fact, that's a book back in 1982, entitled *Risk Benefit Analysis*. It's a -- but the concept is repeated in other references.

Once you've got that and once you're aiming at doing a calculation of risk in this form, you've got to decide what's acceptable. You've got to think, what are you aiming at? How are you going to compare the results of what you get with any sort of standard? And I should say at this point, some sort of peer review is needed.

Now, another problem in communication: Peer review means different things to different people. It's also -- they have a whole manual on how to do peer review. It has nothing to do with scientific peer review. It's just a cookbook on how EPA starters should handle the peer review process. Peer review can be informal, formal, all sorts of things, but it basically involves talking to people and getting feedback. And this initial place is the birthplace -- you need to start talking about peer review, getting feedback on what is the risk that you are interested in. I mean, it makes a very big difference if the introduction of a pest wipes out a crop, versus just has a 10 percent reduction in yield, or a .1 percent reduction in

yield. But how is it that you're going to take that into account?

Now, that's a sort of general statement. I've got my academic hat on: general statements throughout. When you go to a particular pest risk assessment, quantitative risk assessment, the first thing you need is a clear statement of goals for the analysis that you're going to do. You've got to formulate the goals in some way before you can even start.

If you want an example of where, in health risk assessment, people started without formulating the goals, go and look at this NRC 1999. Now, that seems to have nothing whatsoever to do with pest risk assessment. Its title is "Risk-based Waste Classifications in California." However, the concepts within that are entirely applicable. I was surprised at how applicable they are to pest risk assessment, indeed to any quantitative risk assessment.

You've got to start with, what are the goals? For example, are you interested only in the probability of establishment of a pest? In that case, that's not sufficient. You need to define it further. Over what time period? How are you going to handle uncertainty, and does it matter? In what crops and animals? Are you going to deal with only a perfect system or the real-world systems? Does it matter? Well, it does, I would say.

What's the relations of the consequences of the establishment of the pest, and how are those going to be incorporated -- how are the consequences going to be incorporated into the risk assessment? And how are you defining risk in this analysis? I mean, that's one of --

you've got to know what you start -- before you start out, what your aim is. And here again, you need to find out from some sort of peer review, do others agree with you or have you missed something? The only way that you find out you've got something wrong is because somebody else tells you or comes up with a new idea, a new way of looking at things.

Now, I've got to emphasize that, because that's something I saw a complete lack of in evaluating, for example, the Argentina case.

Then you should perhaps -- once you've thought of what your goals are, it might be worth thinking of what they aren't, and then ask yourself, should these things that I've missed out, should they be in there somewhere? For example, are you interested in noneconomic crops or other plant crops? Are you interested in wildlife protection, as opposed to just economic crops? Are you interested in noneconomic measures like distributional inequities. All these things are discussed in some of the references that I talk about.

Once you've defined what the goals are, you've got to think, how am I going to meet those goals? And the usual approach for any quantitative risk assessment can be described as a scenario development. You've got to think of ways of -- how can I analyze in such a way that I can meet my goals? Again, back to 1999, the NRC report. The NRC is National Research Council of the National Academy of Science. I'm sorry, I forgot to mention that. I assume everybody knows, but of course, NRC can also mean Nuclear Regulatory Commission, which is also relevant in this context.

A scenario is really some sort of abstract representation of a real-world situation. For example, it may be descriptive. It usually is. And in this situation, it would usually include a description of a complete set of pathways followed by fruits or pests or whatever you're analyzing, including the nonideal pathways. You've got to do a whole system analysis on what's going on in the world. Ideally, you're understanding how the world works. I mean, that's fundamentally what you're aiming at here. It's impossible, of course, but you try.

The systems you look at must include all the components, including humans, who are fallible, make mistakes. So do machines, sometimes, and must include all the failure modes of the systems. And we've got many examples around us where you've got systems approaches -- your -- and not mine -- to ensuring safety and the reliability issue, for example. For example: airline operations, by themselves; the operation of the whole air traffic control; operating individual airlines; constructing individual airlines; nuclear power plant operation; nuclear power plant safety analysis. That's where the Nuclear Regulatory Commission comes in. A lot of the concepts in quantitative risk assessment were developed in the nuclear power industry, so you should be familiar with that list and should put it down before you even think about undertaking a quantitative risk assessment.

The scenario development -- you've got to develop the scenarios. So you develop your scenario, so what? Well, you've now got to show that they are connected to the goals that you are aiming at. You have got to demonstrate

that all the goals you're interested in are incorporated into your scenarios.

For example, here's a nice tidbit out of that NRC 1999 report: "A poor selection of exposures" -- and I think this was cost risk analysis, so it was exposures analysis; just substitute your own terms -- "might invalidate any conclusions drawn from the assessment." I mean, if you analyze the wrong thing, you can't draw any conclusion whatsoever about the goals you're interested in.

And again, this is a situation where the only way you can be reasonably sure -- you can never be absolutely certain, but you can be reasonably sure that you're looking at the right things -- is by asking everybody else if they can think of any other things that you should have thought of. I mean, that's the only way the probabilistic assessments for the nuclear power plants have developed. I mean, it's been out there for how long now? I don't know. But nobody has come up with any accident scenarios, accident sequences and things, that aren't in that. If they came up with them, they were incorporated or shown to be negligible or shown to be irrelevant.

So the only way to get this right that we know of is to have others criticize it for long enough, and even then you might miss something. But it's experience that counts. And for experience, you've got to have talking to others, peer review. You've got to go back and cross-check what happened before. An example of that in New Zealand -- I don't know if anybody knows about that -- New Zealand did a risk assessment for import of green hides, for the probability of importing anthrax. And just recently --

there's a website discussion of this -- they realized that they'd been analyzing the wrong thing, and so the probability assessment changed from one in so many millions to one in 82 a year, which is slightly large, a large change, and indicates that you've got to get out there and see, are you analyzing the right thing?

Once you've got the scenarios, you now want to think models, model development. How do I model this scenario? It's a separate thing, the model from the scenario. Again, I'm referring to this one because I'm familiar with it, it's recent, and it's got all these concepts in it.

The following sequence of things that I'm going to go through was applied to contaminant transport. It's not with the NRC committee; the NRC committee discussed similar ideas. And I was surprised, when I went and looked at it, that it applied almost at ease to organisms or diseases or pests, to what not, if you substituted the right words. And I took out chemicals throughout, so it was not quite so obvious.

But basically the idea of modeling your scenario is, you identify the physical situations associated with transfer pathways in various scenarios, and the mechanisms that transfer through the pathways. You first identify them, then to the extent possible, you describe them in mathematical terms, hopefully using approaches that are in the literature, but otherwise developing them yourself, as required.

You then develop or simplify mathematical models of these. I mean, you can describe them in mathematical

terms; that doesn't mean that's useful to you, yet. You've got to simplify them. Simplifying mathematical models on correlations as well, that was what was done, for example -- you can think of how that was what was done in the citrus import probabilistic assessment, where this was reduced to simply assuming that you could represent the transport of pests through various parts of a physical situation -- the probability. It's not obvious that that's true, but that was what the simplification was. I don't think the people doing it realized that's what they were doing. But nevertheless, that's how -- you can formalize it in this sort of way.

You then go on to propose algorithms that provide solutions to those simplifying models, and to sufficient accuracy. And then when you've done everything, you want to summarize the expected accuracy of your solution algorithms, principal strengths and weaknesses of them, magnitude of biases in them, if you know of any. You're often biasing, especially in human health risk assessment, you often have built-in biases toward safety. You might want to think what biases do you want to build in, or to -- in pest risk analysis. And it may depend on the situation. You can't necessarily generalize.

What mechanisms have you forgotten? What mechanisms do you know about that you have not included in your modeling, and what's the effect of those? Again, this is a situation where you need peer review. You need discussion with experts in many fields. It's interdisciplinary again. And for example, I've got a series of don'ts based on the Argentine citrus model. Don't assume

a model without demonstration of its validity, as included in your guidelines.

Well, what guidelines are there? You don't have guidelines in quantitative pest risk analysis. There are some guidelines for the qualitative pest risk analysis. Unfortunately, one of the main ones that transfers over into the quantitative side is just wrong.

You cannot necessarily model a pathway as a sequence of independent steps. You've got to prove that. You've got to base your model on what actually happens and then, if it is a sequence of independent steps, great. That's easy to model. But first you've got to verify that that's true. Don't assume a single pathway. I mean, there isn't a single pathway. There's dozens of pathways -- of transport, for example.

Don't assume independence without some demonstration of the validity of that assumption, for example. There are many other such things that peer review will bring down upon you like a ton of bricks, because everybody likes to find things like that in quantitative analysis.

Well, having done this, you've got this wonderful theory or idea. Then what? Well, then you've got to go and look at what are the values of all of the parameters in your models. And where are you going to get them from, what databases?

Again, the concepts are described it in this publication. What data are you going to use? What data are used or "were used," I said here. Generally, in order to have significant review of any sort, you need to provide the

raw data from those databases or at least an access path to the raw data. How are those raw data interpreted? You've got to provide the protocols under which the raw data were obtained, or at least an access pathway to them -- that is, a citation of some sort. Because who knows if those were, in fact, interpreted correctly? If they're in the published peer review literature, then there's at least a chance that they were interpreted correctly. But if not, there's a very good chance that they weren't interpreted correctly.

How did anybody come up with the parameter values from this raw data or from the database? Those parameter values should correspond to the model analysis that we just discussed. I mean, the models evaluating the raw data should be fundamentally the same ones as are included in your modeling scenario. It's no good if they are different things.

There's some nice examples in NRC, in the context of house risk assessment, where you've got wonderful raw data and you've got a wonderful model, but the parameters evaluated from the raw data didn't correspond to what was required by the model. They're the right parameters for a different situation.

So you've got to demonstrate that the data correspond to the model. Now, your parameters have got to correspond to the model, and also the data have got to correspond to the model you're using, under the conditions of the scenario that you're analyzing. That can make a difference, too. And once again -- I'm going to emphasize it over and over -- you need to talk about this. You need to get feedback. Does everybody agree with you? It's the

disagreements that help you, because they point out where you've probably missed something.

For example, in the Argentine citrus case, there was a failure to provide any explicit connection whatever between any data and the parameter values that were used, throughout. And it helps, also, if you don't make parameter estimates that are contradicted by the available database, which again, I believe, I have got up there. I can't be absolutely certain. Don't evaluate the wrong parameter from the right data. That's something I've just mentioned. There are some examples of that. And if you're doing probabilistic calculations, you can't make arbitrary distribution or something. You've got to have some basis.

Now, certainly in pest risk analysis, from what I've seen, you're going to have a broad use of expert judgment. Well, that's not unusual. There are whole systems and ways of getting at expert judgment. You need to know who are the experts, to be able to do a -- up. You need to know, what evidence are they basing their judgments on. For example, the Kaplan approach was claimed to be used in the Argentine assessment, but there was no documentation of the evidence, which is an essential part of his approach.

Now, there are other approaches to debriefing experts, as well. But in every case, you need documentation of what was done and how. Why did the evidence [sic] say what they do say? What inference methods are they using or, if necessary, what formal inference methods are being used on the evidence of the experts?

Can other fields provide an insight here? Well, there's a very useful discussion in the 1995 National

Research Council discussion which was called, this was entitled "Science and the Endangered Species Act." Now what has pest risk analysis got to do with the Endangered Species Act, you might say. Well, they were talking about risk assessment, too. They were talking about the obverse of what APHIS is trying to do. They were trying to ensure the conservation of the species, not wipe it out, or ensure that it stayed wiped out, or would never be established. So there are some very useful insights in the modeling described there and in the risk assessments they review. For example, variability from year to year makes a very large difference for endangered species, but it also may make a similar difference for ensuring the lack of establishment of a species. So there may be other fields with very useful insight.

And again here, this is where peer review is -- I mean, you can't even start without it. You need to have -- and conferences and database examination, interpretation, and conflicting viewpoints brought to bear on this, because experts are very often wrong, especially in doing quantitative assessment.

And again, a couple of don'ts, as in the Argentine citrus case. They failed to document who was saying what or failed to provide the evidence that we're talking about.

Well, now we've got the system, we've got the experts debriefed, we've got it all set up. Now what? Well, now we've got to implement it. This gets down to practical retypes. How is it all implemented? What error checking was built in? You would not believe the number of

errors that I find in quantitative risk assessments. Maybe you would, maybe you've looked at some.

The -- I mean, even a simple spreadsheet is next to impossible to set up right the first time. You may think you can do it, but you try it and get somebody else to check it, you'll find something wrong. And if you're -- , how available is that implementation so somebody else can check it? Well, I've never seen an implementation of the Argentine assessment. It's trivial to do, but that doesn't mean it was right. You look at the NRC 1999 publication, they've had just as trivial things and they were wrong.

There's data errors, there's formula input errors -- they're very common in all these things. So it's essential that you provide the implementation that you're relying on. Preferably, you do it two separate ways, at least. Then get somebody else to do it, and preferably you incorporate a formal error-checking process into the procedure. I mean, this is just -- that you apply to implementation.

So that's really, I mean, the concepts. I mean, how do you go about ensuring that you followed some sort of process like this? Well, there's the possibility of guidelines. A 1983 document from the National Academy discusses that in the context of risk assessment. This one is "Risk Assessment in the Federal Government, Managing the Process," 1983. It talks about guidelines and, in particular, about inference guidelines. Now, here we get another matter of not understanding each other's language. I didn't realize this until I got the document. Guidelines means different things to different people. The legal

people have one meaning. The physical scientists have another. I'm talking about the physical scientist's meaning of guidelines.

You've got to think, are they necessary? Well, they probably are a necessary evil. They're an evil because you get guidelines which then have to be used as defaults and nobody can ever change away from it. That's happened a lot where they have a set of guidelines and nothing ever gets done, except following exactly those guidelines, even when they're completely wrong. And as I said, the available nonquantitative guidelines for pest risk analysis are invalid for quantitative risk assessment.

The useful -- it's useful always to know the context. What is the history of pest risk analysis? Well, I've found it impossible to find out without asking anybody in APHIS directly -- I don't know if it would work even then -- how many has APHIS done? I found two I have access to, and I found a reference to a third. Any advance on three? Is there an index somewhere? I mean, how is any peer reviewer going to come into this field without -- if risk analysis and risk analysts, in general, haven't been in this field. They've got a lot of useful inputs for you, but they can't find anything.

What databases do you use? Are they available -- on the web, that means, nowadays. There's no reason why databases shouldn't be available on the web. Where is the cross-referencing to other assessments, to other countries' assessments? Any mention of that New Zealand thing anywhere? No one.

So, yes, who else has done similar things? Other countries and national agencies. Have they got any good ideas? That's the whole idea of this game -- you steal somebody else's good ideas. That's what all of science is --

(Laughter.)

DR. CROUCH: -- I mean, if you think about it. Documentation: essential. The ideal of documentation for any risk assessment, almost any qualitative -- on any pest risk analysis or anything else -- you should be able to, an independent outsider should be able to come in and reproduce the whole analysis from the documentation, starting with the raw data or the expert evidence, starting with expert evidence.

Ideally again, it should all be available on the web. Now, this is impossible -- well, the ideal is never attainable. Some agencies of the federal government and some of the state governments are attempting to do the right things. Some of them are already doing the right things, close to the right things, anyway.

We've heard already about the EPA and the Food Protection Act. The Food Protection Act, the EPA didn't know how to implement it. So what did they do? They asked. They got a whole lot of consultants to come to the symposiums to tell them. I mean, they didn't believe that any individual expert would tell them the ideal answer, but this is what they started with, and that's the right approach. It would help if they got a lot of funding out there, as well, to do it. I mean, consultants were given no

funds to do things, which is not easy. We do some things for free, but not all.

EPA has been approaching the ideal on some things. For example, the initial approach to the Hazardous Waste Identification Rule was very good. They thought, this is a complicated risk assessment; basically, it's risk assessment, the basic rules for hazardous waste, so identify, what is hazardous waste? How do you know?

And they approached the industry very early. There was an advance notice of -- probably years in advance of the proposed rulemaking, which was first proposed in 1985. I think we got into it in 1983, or something like that, as a consultant after some time.

But they made everything available and were open to feedback from -- I think it was actually a consortium with the Chemical Manufacturers Association. There was some disgust, of course, at first, that we had retained them. Some programs are very well documented with material available on the web. The air programs, for example, got very good documentation on the web. So it can be done. I mean, at least you can approach it without too much difficulty.

There are some useful references -- well, I thought of the following from the National Academy, because the National Academy has been asked difficult questions by other agencies doing similar sorts of things. It doesn't look similar at first, but it is, in fact, similar, if you look at them and twist your point of view a little bit.

Starting in 1983, this document still has things to tell us about the risk assessment in the federal

government, managing the courts. It at least puts you on the same -- helps you to understand the words used and the definitions and the fact that people have different definitions of different things.

There's a followup to that in 1989, "Improving Risk Communication," which again, also is highly relevant for the purposes of this meeting. And "Science and Judgment in Risk Assessment" in 1994. Same sort of problems, advising in the health risk assessment field, and again, the National Academy.

The one I mentioned there, "Science and the Endangered Species Act" -- you find interesting things in weird places, that may be relevant and may be applicable here. 1996, "Understanding Risk in Forming Decisions in a Democratic Society," also is very useful. The latest one I'm aware of for its use -- I was involved in it so I know that this was useful -- it's the "Risk-based Waste Classification in California," where exactly the same things that I've been through here, had not been thought about before they started doing something -- they started doing something before they thought about it.

The difficult thing is the thinking hard about it in the beginning, to know what it is that you're after. And I can't do better than to quote the main point of the summary of the 1996 "Understanding Risk in Forming Decisions in a Democratic Society," because really almost everything I've covered here, not in so many words, but they boil it down extremely well and it's worth looking at just for that.

They've got seven main points that they want to get across. "Risk characterization should be a decision-

driven activity directed towards informing choices and solving problems." You've got to know what it is you're after. "Coping with a risk situation implies a broad understanding of the relevant losses, harm, or consequences to the interested and affected parties." What is the risk? What matrix are you looking at, or matrices? No single thing, necessarily.

The next one is rather long. "Risk characterization is the outcome of an analytic, deliberative process. Its success depends critically on systematic analysis that is appropriate to the problem, responds to the needs of the interested and affected parties, and treats uncertainties of importance to the decision problem in a comprehensible way. Success also depends on deliberations that formulate the decision problem, guide analysis to improve decision participants' understanding, seek the meaning of analytic findings and uncertainties, and improve the ability of interested and affected parties to participate effectively in the risk decision process. The process must have an appropriately diverse participation or representation of the spectrum of interested and affected parties, of decision makers, and the specialists in risk analysis, at each step." Oh, that was a long one. Hopefully, the others aren't quite so long.

"The analytic deliberative process leading to a risk characterization should include early and explicit attention to problem formulation. Representation of the spectrum of interested and affected parties at this early stage is imperative. The analytic deliberative process should be mutual and recursive. Analysis and deliberation

are complementary and must be integrated throughout the process leading to risk characterization. Deliberation frames analysis, analysis informs deliberation, and the process benefits from the feedback between the two."

And they have a wonderful sentence that I thought really encapsulated some of what I've been saying: "First, it's getting the science right; second, it's getting the right science; third, it's getting the right participation, and then it's getting the participation right; and then developing an accurate -- and informative synthesis." It's a synthesis.

"Those responsible for risk characterization should begin by developing a provisional diagnosis of the decision situation, so that they can better match the analytic, deliberative process leading to the categorization to the needs of the decision, particularly in terms of level and intensity of effort and representation of parties. Each organization responsible for making risk decision should work to build organizational capability to conform to the principles of sound risk characterization. At a minimum, it should pay attention to organizational changes and staff training efforts that might be required, to ways of improving practice by learning from experience, and to both costs and benefits in terms of the organization's mission and budget."

I would suggest that that document, the National Academy document, should be closely scrutinized.

And thank you for putting up with me with my academic hat on this morning. Thank you.

(Pause.)

MR. LIDSKY: Dr. Crouch, thank you. You certainly provided sufficient food for thought. Thank you for your written text.

Today's proceeding does not only provide an opportunity for a dialogue between other people that have heard your presentation and may agree or disagree -- and that opportunity will certainly present itself at the symposium that we're planning, and we look forward to everyone in the room attending and certainly continuing this dialogue.

We have one more speaker and that is Mr. Ted Batkin. And then we'll ask for unregistered speakers.

MR. BATKIN: Well, thank you very much, Dr. Lidsky and panel this afternoon -- excuse me, this morning. It's afternoon somewhere, probably in London.

I've been very interested sitting here listening to the perspective of the presentations today, and one would think that this is a citrus problem, if you were to listen. I thank Craig for being from the American Landscape and Nursery Association, to give us a little broader perspective.

My role is that I'm the president of the California Citrus Improvement Program, but I'm going to be speaking today on a little broader perspective, and that is, my position as chair of the California Commodities Committee, which represents 46 different state research organizations of different commodities in California; also, my role with the U.S. Exotic Fruit Fly Coalition and the National Citrus Research Council. And the reason I've pointed all of those out is that there's a lot of titles

floating around and there's a lot of people representing organizations, and I've always been asked -- I've been in the research management industry in California for 18 years -- and the question always comes up, who represents who? And there is one conclusion we've come to in California. With 256 different commercial horticulture crops that we grow in the state, nobody represents anybody. We're just all kind of a confused mess out there.

But with that said, there is one consistent statement that can be made, and I think Nancy Williams summed it up the best in her comments regarding what are the concerns of the industry. And that is that there is a tremendous focus and a tremendous spotlight on the risk assessment system, as it stands today, and the need for changing or, better put, improving the risk assessment process.

I'm not going to go into any details. I think Dr. Crouch did an excellent job of detailing some of the issues that are in front of us. I just think that those comments need to be taken into consideration and I'm looking forward to the symposium that will do that.

As Craig mentioned, there is a safeguarding alliance that is put together to address some of the broader issues in improving APHIS and improving the systems, and one of those happens to be resources. A number of the speakers have talked about resources and there are, obviously, going to be more resources that are going to be necessary to move the process in a positive direction. The safeguarding alliance is made up of national organizations that will make it their mission to do whatever it takes to see that

additional resources are put into the baseline budget, so that these steps can take place.

There's another recurring theme that flows throughout the industry and it doesn't matter whether you're from the left coast or the right coast or somewhere in the center. And that is that risk assessment and the entire risk analysis process must be based on sound science, not political science. Political science has driven the system for years, and there are still many in the system that think it still runs that way. However, with the advent of the SBS agreement and the WTO, that it is absolutely necessary that the future, in order for us to maintain a level playing field both in exports and imports, must be based in sound science.

The problem of the dichotomy between safeguarding and improving trade is one that is always going to be facing APHIS. That's not going to go away, even though we would like to see it happen.

However, during the development of the safeguarding review, we've found that they are not mutually exclusive, that they can be compatible, and that using good sound science and risk analysis will, in fact, increase the ability for the U.S. to increase their trade.

As APHIS goes through their deliberations in looking at what improvements need to be made to the pest risk analysis, I want to echo what was said earlier on the language of pest risk analysis being defined. I have been confused from day one, and I'll go back to the avocado importation issue, on what a systems approach is. I've spent 18 years as a scientist managing scientific review

programs, and I'm still confused as to what the definition of that is.

There are additional definitions that, as Nancy and others have pointed out, must be clearly defined so that the industry and the stakeholders understand what is going on within the process.

I think it's very clear that the more understanding that we all have of what the rules are, the clearer we will be able to participate in making progress, as opposed to fighting with each other over what the different terms are.

One of the other things we discovered in the review process was that it's necessary for APHIS, in their process, to step back and take time for critical thinking. We recognize that due to constraints in resources and time and availability, that there is not time for critical thinking, especially when you're faced with a backlog of two to three years of risk assessments that must be completed. And to step back and say, how do we approach these properly sometimes is a luxury that you don't always have.

But in the process and in the thinking, I think it's important that the risk assessment people involved in this, step back and see who is at risk. If you wonder why the industry is always complaining and always throwing barbs and saying this has to happen or that has to happen, it's because we're the ones that are at risk. And it's an old and tired cliché over who is involved in the ham and the eggs.

It's quite clear that the chickens are involved, but the industry are the pigs. We're committed to the ham.

And if something goes wrong with risk assessment, we don't just shift gears and go on to the next paper that crosses our desk. We have to go out and figure out what we're going to do with this farm that we can no longer farm or this industry that is collapsing around us. So we have a very emotional involvement in the debate and in the discussion.

In concluding, I'd just like to say that it takes time to make improvements. I think many of us as growers, especially if you're vegetable growers whose long-term planning is three months -- their short-term plan is, can I get through the day -- everybody wants instant gratification and a solution. It's kind of like driving a speedboat. When you get in a speedboat and you want to turn, you turn the wheel and the next nanosecond, you're going off 90 degrees to the right.

But in order to change and improve a system as large as the risk assessment program, we all, including the industry members, must remember that it's a long-term solution and instead of turning the speedboat on a nanosecond response to the wheel, it's like driving the Queen Mary. And the process of turning the Queen Mary takes a very long time. It's called advance and transfer, in nautical terms. First, the order has to be given by the officer of the deck. That order then has to be interpreted by the helmsman who will turn the wheel. Well, it will cause a whole series of physical activities to occur within the ship, and about a half an hour later, the ship starts to turn. And that requires planning and advance thought in order just to make a very simple course correction within the ship.

As that as an analogy, I think it's very important that we have the patience to work through the system to allow the safeguarding review to take place, and for everyone committed to the issue of change in the safeguarding review and in the risk assessment process to be given the time to analyze it accurately and not make critical mistakes along the way. Thank you.

MR. LIDSKY: Thank you very much, and we really appreciate your analogy. It's a good one. Are there any persons that are not registered to speak that would like to share some comments with us?

(Pause.)

MR. LIDSKY: Well, it appears not. I want to thank everyone for coming today. It's these comments and these opportunities that give us the information that we need to hopefully do the right job and we are certainly going to take the time to take all the comments into consideration. We're going to continue this dialogue at the symposium in 2000, and believe me, we are committed to doing it right. Thank you very much.

(Whereupon, at 11:44 a.m., the hearing in the above-titled matter was concluded.)

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